

## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Addiese: COMMISSIONER FOR PATENTS PO Box 1450 Alexandra, Virginia 22313-1450 www.wepto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,698	07/03/2003	Bhiku G. Patel	03-40102-US	7194
7590 07/21/2009 William J. McNichol, Jr., Esquire			EXAMINER	
Reed Smith LLP 2500 One Liberty Place 1650 Market Street Philadelphia, PA 19103-7301			GHALI, ISIS A D	
			ART UNIT	PAPER NUMBER
			1611	
			MAIL DATE	DELIVERY MODE
			07/21/2000	DADED

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

1	RECORD OF ORAL HEARING
2	UNITED STATES PATENT AND TRADEMARK OFFICE
3	UNITED STATES FATENT AND TRADEMARK OFFICE
4	BEFORE THE BOARD OF PATENT APPEALS
5	AND INTERFERENCES
6	<del></del>
7	Ex parte BHIKU G. PATEL, MOHAN VISHNUPAD,
8	EUGENE H. GANS, and KULJIT S. BHATIA
9	
10	Appeal 2009-001871
11	Application 10/613,698 Technology Center 1600
12	
13	0.111 - 1.111.1 - 25 2000
	Oral Hearing Held: June 25, 2009
14	
15	Before DEMETRA J. MILLS, LORA M. GREEN, and MELANIE L. McCOLLUM, Administrative Patent Judges.
16	MELANIE L. MCCOLLOM, Administrative Patent Juages.
17	APPEARANCES:
18	ON BEHALF OF THE APPELLANT:
19	
20	William J. McNichol, Jr., Esquire REED SMITH, LLP
21	2500 One Liberty Place
22	1650 Market Street
23	Philadelphia, Pennsylvania 19103-7301
24	
25	
23	

1	<u>PROCEEDINGS</u>
2	MS. BEAN: Calendar No. 67. Mr. McNichol.
3	JUDGE MILLS: Okay, thanks.
4	MR. McNICHOL: I can only hope to be as persuasive as the last guy.
5	He looked good.
6	JUDGE MILLS: He was quick, wasn't he, though? In and out.
7	MR. McNICHOL: Okay. This appeal is in a case involving an
8	invention that is an improved drug delivery system. It's more effective than
9	the prior art in delivering insoluble particles to the skin. Some drugs, many
0	drugs, are delivered in solution, but others are delivered as insoluble
.1	particles, and the example that I'm going to show you today is benzoyl
2	peroxide, which is an acne treatment, but there are others. You ever see a
.3	lifeguard sitting in the lifeguard stand with that white stuff on his nose?
4	That's zinc oxide, and it just physically blocks the sun. Those are insoluble
.5	particles.
6	To get something applied to the skin using a pad, if it's a solution it's
.7	not a big deal, but if it's a particle problem and this is identified in, among
8	other places, paragraphs 5 and 8 of the spec, is that the paper or the pad
9	tends to act as a filter paper, if you will, and holds the particles, those
20	insoluble particles, in the nap of a cloth, and it doesn't get off the cloth and
21	onto the skin.
22	JUDGE MILLS: Just for clarification, your claims don't recite
23	particles, do they?
24	MR. McNICHOL: Yes, they do. Yes.
25	JUDGE MILLS: Oh, claim 1?

- 1 MR. McNICHOL: Claim 1 refers to --
- 2 JUDGE MILLS: Ingredients, active --
- 3 MR. McNICHOL: -- insoluble, dermatologically active ingredients.
- 4 JUDGE MILLS: Okay.
- 5 MR, McNICHOL: Okay, and in --
- 6 JUDGE MILLS: But not particles.
- 7 MR. McNICHOL: -- the dependent claims refer to benzoyl peroxide
- 8 particles of certain sizes and such as that, yes.
- 9 JUDGE MILLS: Okay, very good. Thank you.
- MR. McNICHOL: Yes. So the problem is kids actually don't like to
- 11 carry bottles of benzoyl peroxide around with them but pads they can --
- 12 which they can tear open and wipe on their faces is terrific. The problem is
- 13 the insoluble particles don't get off the pad or get off the pad very
- 14 inefficiently. This invention solves that problem by manipulating two
- 15 variables that were not known to have any effect on this, and as part of the
- 16 specification we submitted because it was fluorescent color photographs,
- 17 and you can see how well the particles are deposited onto the skin.
- 18 If you'd like, I could pass this up if that would be of any, you know, interest
- 19 or use.
- 20 JUDGE MILLS: Can I just -- if you could just clarify me --
- 21 MR. McNICHOL: Sure.
- 22 JUDGE MILLS: -- for me. You're not conceding the prima facie
- 23 case with respect to the dermatologically active ingredients? You keep
- 24 referencing particles, and I want to make sure --
- 25 MR. McNICHOL: Right.

1 JUDGE MILLS: -- we're talking about claim 1 here in the 2 independent claim. 3 MR. McNICHOL: Insoluble dermatologically active ingredients. 4 JUDGE MILLS: Okav. 5 MR. McNICHOL: Yes. Not dermatologically active ingredients in general, only the --6 7 JUDGE MILLS: Insoluble, yes. 8 MR. McNICHOL: -- only the ones that are insoluble, yes. 9 JUDGE MILLS: Okay. 10 MR. MCNICHOL: The prior art never recognized that by controlling 11 viscosity and additionally particle size, okay, or both viscosity and particle 12 size, you could keep the particles from getting trapped in the applicator pad 13 and off the pad and onto the skin. The Examiner has cited several references, and I think that the Examiner has misconstrued frankly all of 14 15 them, okay. 16 The first reference that the Examiner cites is the Smith 642 patent. 17 The Smith deals mostly with gels by its terms, it says that, but does mention 18 emulsions, and by the way, the claim requires that this be an emulsion of a 19 certain viscosity, okay. But at no point does the Smith 642 disclose in any 20 way that the viscosity of the final product matters or what it is. Smith does 21 disclose in some places the viscosity of some of the ingredients as they sit in jars before they're mixed in, okay, but Smith doesn't mention what the 22 23 viscosity of any of Smith's end products are or whether that makes any 24 difference at all, no awareness of that concept at all. Smith doesn't --25

25

much, okay.

1 JUDGE GREEN: But that doesn't really matter. That doesn't matter 2 if it's an inherent property, correct? I mean our problem is we can't go take 3 the Smith product and test it and figure out what the viscosity is. I mean but 4 if their viscosity matches -- is the viscosity that would fall within your range. 5 it's inherent, right, and you don't -- they don't have to disclose it. 6 MR. McNICHOL: They -- if Smith disclosed a product that had the 7 viscosity, okay --8 JUDGE GREEN: But they don't have to measure the viscosity if it 9 was an inherent property of that product. MR. McNICHOL: Right, but you can't assume that it does have that 10 11 viscosity. 12 JUDGE GREEN: But how do we figure it out whether or not it has that viscosity? 13 14 MR. McNICHOL: You can't make the assumption, okay. If Smith 15 doesn't disclose it, okay, and nobody suggested that Smith explicitly 16 discloses it, okay, you don't know it. I don't know it. You can't just 17 speculate that maybe it does. 18 JUDGE GREEN: Well, then how can we have cases like Best that if. 19 you know, that there's enough evidence that it more likely than not has this 20 property --21 MR. McNICHOL: I don't think there is such a thing, and this is really an important point, and I think you've zoomed in on one of the -- perhaps 22 23 the central issue of the case. But the assumption simply proves way too

## Appeal 2009-001871 Application 10/613,698

- 1 Now we point out in I think it's at page 20 of our brief, okay, another patent,
- 2 prior art patent that exists in the record, the Bissett patent, the 237 patent,
- 3 and like the Smith 642, Bissett discloses, and I'll point you very quickly to
- 4 the specific provisions of portions that I have in mind, they disclose an
- applicator pad, at column 22, is in a container, the dispenser. That's 5
- bridging columns 22 and 23. They disclose insoluble particles like zinc 6
- 7 oxide, titanium dioxide, zinc metal, okay, in an emulsion, okay, all right,
- 8 with all the same emulsifying ingredients --
- 9 JUDGE McCOLLUM: Can I stop you for a minute?
- 10 MR. McNICHOL: Yes.
- 11 JUDGE McCOLLUM: Is the Bissett on the -- is that a reference
- 12 that's on the -- on this record?
- 13 MR. McNICHOL: It is, and it was discussed in our opening brief at
- 14 page 22.

20

- 15 JUDGE McCOLLUM: It's not -- and is it a -- I'm not seeing it real
- 16 quick in our file, but that doesn't mean --
- 17 MR. McNICHOL: Yeah.
- 18 JUDGE McCOLLUM: Okav.
- 19 MR. McNICHOL: It is just for reference patent no. 5,821,237. Okay.

So just to very quickly recapitulate, it's a pad with an emulsion on it

- 21
- in a container, in a dispenser container, with insoluble active particles, and
- 22 they enumerate several like zinc oxide, titanium dioxide in column 20, zinc
- 23 metal in column 14, and their emulsions, and they use all the same
- 24 ingredients that are mentioned as being useful in emulsions in -- so by that
- 25 reasoning. Bissett would be possibly even an anticipatory reference, okay.

- 1 But you'd be wrong if you made that assumption, because at column 13 of
- 2 Bissett, they tell you what their viscosity is. It's something like quarter
- 3 million centipoise -- excuse me, 200,000 centipoise, okay, which is way
- 4 beyond our claimed ranges, okay.
- 5 And this is a point where the facts of a specific case illustrate the error
- 6 of a legal approach that the Examiner is taking. You don't make
- 7 assumptions that are unsupported by the facts in front of you, because if you
- 8 could excise the portion of Bissett that says and by the way, when I do it I
- 9 get like 200,000 centipoise. You think oh, well, Bissett must have had
- 10 viscosity in Dr. Patel's range. Well, it's not true, and that's why you don't
- 11 make those assumptions.
- 12 JUDGE MILLS: Can you give us an idea or does the specification
- 13 give us an idea of what you are referring to when you speak of a low enough
- 14 viscosity for the composition to substantially --
- 15 MR. MCNICHOL: Sure.
- JUDGE MILLS: -- uniformly absorb to the pad and high enough -- I
- 17 mean you obviously believe that --
- 18 MR. McNICHOL: I'll refer you -- I will refer you to claims 8, 9,
- 19 10 --
- 20 JUDGE MILLS: Oh, okay.
- 21 MR. McNICHOL: -- 11, 12, there may be more, but yes, and the
- 22 supporting disclosures in the specification. Absolutely.
- 23 JUDGE MILLS: Okay, much lower than --
- 24 JUDGE McCOLLUM: Now just talking about Bissett now, it's a
- 25 very high viscosity, so it's clearly high enough to be substantially retained

- 1 by the pad but presumably not low enough? I'm going with claim language
- 2 here.
- 3 MR. McNICHOL: Claim 1.
- 4 JUDGE McCOLLUM: Yes, claim 1.
- 5 MR. McNICHOL: Right.
- 6 JUDGE McCOLLUM: It's not low enough for the composition to be
- 7 substantially uniformly absorbed onto the pad via capillary action? Is that
- 8 what you're saying?
- 9 MR. McNICHOL: That would be our point --
- 10 JUDGE McCOLLUM: So it's on the pad but it -- the -- you're saying
- 11 that somehow it gets there by some other means than capillary action I
- 12 guess.
- 13 MR. MCNICHOL: It's so thick it just adheres to it, but it doesn't get
- 14 on by capillary action, that's correct.
- 15 JUDGE McCOLLUM: Okay.
- MR. McNICHOL: And again, you're analyzing claim 1. You're not
- 17 dealing with claims 8, 9, and so on which --
- 18 JUDGE McCOLLUM: Right.
- 19 MR. McNICHOL: Clearly, we're dealing with numerical situations
- here that provoke a different analysis than the one you have just walked usthrough.
- zi unougn.
- 22 JUDGE McCOLLUM: Right, and I -- right, but you know, that's the
- 23 harder case, and I think that's --
- 24 MR. McNICHOL: Claim 1 always is the harder case.

24

25

1 JUDGE McCOLLUM: -- clearly obviously it doesn't teach the range 2 or it, you know -- I mean, it's not applied, but would it teach the range of 3 claim 8, you know, no one is applying it against claim 8. So our question --4 MR. McNICHOL: Right. 5 JUDGE McCOLLUM: You know, the only thing I want to point out is we're trying to figure out what the range would be so we can say with 6 7 any confidence that it doesn't meet that range, and that's what the Examiner 8 I think is struggling with, especially like, for example, the Delambre 9 reference. It teaches 150. The question is in my mind is how is he supposed 10 to know that 150 is not high enough to be substantially retained on the pad, 11 not the container? 12 MR. McNICHOL: I think you have to go with the specification, and I 13 think paragraphs 27, for example, give you some guidance with respect to 14 that. 15 JUDGE McCOLLUM: Right. 16 MR. McNICHOL: I don't think that it's --17 JUDGE McCOLLUM: They give you guidance as ranges that would 18 have --19 MR. McNICHOL: Yeah. 20 JUDGE McCOLLUM: -- this property, but they don't really give you 21 a lot of guidance as to what wouldn't have the property. 22 MR. McNICHOL: Sure. I don't think that a person skilled in this art.

9

a formulator, will have any difficulty identifying that without any serious

trouble. You know, I mean think functional language which the Examiner

seems to discount as not even being a material limitation, that's clearly

1 wrong, but I don't think that a formulator in this field would have any 2 difficulty determining that. 3 JUDGE McCOLLUM: Oh, I agree that a potential infringer can 4 easily test his product. The question is more how the Examiner can 5 determine whether 150 is high enough to -- so that he can know whether to allow claim 1. 6 7 MR. McNICHOL: I see your point. I think certainly the Delambre 8 does not say that that's going to happen, okay, and it's certainly our position 9 we're estopped at this point to ever assert that a viscosity that low would 10 ever reach it, so I don't think that the -- in terms of the notice function of 11 patents and patent claims is a concern there's any serious concern with 12 respect to that, and I think that, you know, to a formulator of products who 13 wants to know whether they fall within the patent, I think it's an afternoon's 14 idle work to accomplish that. So I don't think that the notice function of the 15 claims is in any way compromised by doing that. 16 But I think the point -- we've zoomed in, Judge Green, on exactly the 17 central, and I think there are other points that are important and need to be 18 addressed, and I hope I'll have a chance to do that. But I think the flaw that 19 the Bissett patent illustrates is that you cannot make a guess. You have to 20 look at a patent for what it discloses, not what you think it might disclose or 21 the possibilities of what might be disclosed. If in hindsight you're armed 22 with the knowledge that viscosity is, if you allowed a result-effective 23 variable and be -- there's a range that you want to get into, okay. Only with 24 that lens can you go back to Smith 642 and say oh, we must have been, you

know, and then you got to ignore Bissett.

1 JUDGE GREEN: Well, I -- the result-effective variable I agree with 2 you on, because that's more of an obviousness type thing, because it would 3 be obvious to optimize, and you have to have something to point you to the optimization. The problem is the inherency, because I think what we've 4 5 been -- we're talking about is that this is a very hard claim for the Examiner to search, and he can't go out and test these products. 6 7 MR. McNICHOL: Understood. 8 JUDGE GREEN: While it may be an afternoon for a formulator, the 9 Examiner, you know, has his computer and the writings and the -- so we're 10 just trying to get a better handle of what the claim encompasses --11 MR. McNICHOL: Sure. 12 JUDGE GREEN: -- so that we can go back through these references 13 and see what they would suggest to the skilled artisan. 14 MR. McNICHOL: Right. And just so you know, when you're 15 advising a client whether a particular claim might be patentable, all I have is 16 my computer too. So I understand the difficulty. But the law requires us to 17 operate within the disclosures of the patents, and you have to operate with 18 Smith not in a vacuum but Smith sitting as, if we borrow Judge Rich's 19 phrase about the Winslow tableaux of all the prior art pasted on the wall 20 around you, Smith's disclosures don't tell you anything about viscosity, 21 okay. They simply don't, okay, of the finished product. And so you can't 22 look at Smith and just say well, if Smith knew to make it in that viscosity 23 range he might have, and so it anticipates the claim, okay. 24

1 And by the way, Smith's disclosures with respect to benzoyl peroxide 2 products are prophetic. I mean there's no working example in there, okay, 3 to my knowledge. 4 JUDGE GREEN: But what we're worried about I think is the 5 inherent anticipation and the accidental anticipation, because they don't have to know about viscosity. They don't have to know that it's important to 6 7 come up with --8 MR. McNICHOL: Agreed. 9 JUDGE GREEN: -- a product that falls within the scope of your 10 claim 1, and that's what we're trying to figure out. 11 MR. McNICHOL: I understand that, but there is no working 12 example. For example, if you looked at Atlas Powder, okay, and if you 13 looked at *Perricone v. Medicis*, okay, a case which I litigated in the federal 14 circuit, in each of those cases. Atlas Powder there was a chart that had the 15 quantities of each of the ingredients, okay, and you could tell that if you did 16 that you fit within the range limitations of the claim, and somebody claimed 17 that if you did that you'd get a great effect and say well. Atlas Powder got 18 that effect because it was -- air and prills and stuff. Same thing with -- in 19 Perricone v. Medicis. That case you had somebody putting together 20 ingredients in stated amounts in a stated product and applying it to skin. 21 There was nothing there. These were actual working examples. 22 Here you have prophetic statements, or if you will paper statements. 23 about all the different possible things that could happen, okay, and we know 24 for a fact, because Bissett illustrates this fact, that there is no reason to 25 assume that that's going to be anywhere near our viscosity range. So you

- 1 know, the law just doesn't let you go that far. Okay, because if Bissett, for
- 2 example, had not included that little section of just six lines where he
- 3 actually told you what his viscosity was, you'd be using it for the same
- 4 purpose that Smith did and somebody would be -- we would be told you
- 5 have an anticipatory reference, no patent. But in truth, there was no
- 6 anticipation --
- 7 JUDGE GREEN: Well, no, that's not what you're told. What you're
- 8 told is these appear to be the same. You need to go back to your lab and
- 9 provide us the data to show us that they're not, I mean because that's
- 10 really -- it's just a burden shifting.
- 11 MR. McNICHOL: Well, it -- I don't think there's any case at any
- 12 level, either at the Board or at the federal circuit, that establishes that, that if
- 13 the Board or the Examiner thinks that maybe something might have
- 14 happened --
- 15 JUDGE GREEN: No, I agree but you -- but based on Bissett, if
- 16 Bissett hadn't had that line in there as to the viscosity, that it is the same
- 17 composition, it's an emulsion --
- 18 MR. McNICHOL: Right.
- 19 JUDGE GREEN: -- same active ingredients and everything else, I
- 20 think that you would have enough evidence to show by a preponderance of
- 21 the evidence that more likely than not that these appear to be the same.
- 22 Therefore, the burden is shifted to you, applicant who has the testing
- 23 facilities, to come back and do the test and say no, it falls outside our
- 24 viscosity range.

1 MR. McNICHOL: I disagree with all -- because I think we all have 2 sufficient familiarity with viscosity and how it's affected by quantities of 3 ingredients to know that unless you know how much of each ingredient is 4 used, you can get any number of different readings. 5 JUDGE GREEN: Well, but I'm saying you would have to compare it to something that they had --6 7 MR. McNICHOL: But there is nothing to compare it to in Smith 8 642 ---9 JUDGE GREEN: No, I'm talking about your hypothetical in Bissett. 10 MR. McNICHOL: Okay. Even --11 JUDGE GREEN: Because he tested something. 12 MR. McNICHOL: Yeah, but even Bissett, okav, didn't test that 13 particular formulation, okay. He says I want my formulations in this range. and that's the way you do them, okay. So that's generalization he's making 14 15 about all of this. But getting back to our case here, Smith doesn't give me anything to recreate. There isn't an example X, okay, that's in there but just 16 17 doesn't have the viscosity mentioned. That would be the case -- that would 18 be Atlas Powder. That would be Perricone. 19 JUDGE GREEN: Yeah, I understand that. 20 MR. McNICHOL: Okay. 21 JUDGE GREEN: If it's totally hypothetical and totally --22 MR. McNICHOL: Right, yeah. 23 JUDGE GREEN: -- I understand you need to have something to 24 compare to.

24

25

2 compare to, and how I reconstructed, I mean if -- I think we all understand 3 that if I want to reconstruct Smith so that it's like maple syrup in January I 4 can. If I want to reconstruct Smith so that it's like running water I can. 5 Smith doesn't give me any guidance. Smith doesn't even know that the viscosity of the finished product counts worth a darn. So there would be no 6 7 reason based on Smith to do it anyway. JUDGE GREEN: What about your remaining references? 8 9 MR. McNICHOL: Sure. 10 JUDGE MILLS: Yeah, we have about 5 more minutes if you'd like to 11 address the other references. 12 MR. McNICHOL: Clearly, I'm not as concise as the last guy. 13 Another problem that kind of runs through these is particle size, okay, which exists with respect to certain of the dependent claims. The Examiner 14 15 has confused the size of the included phase in the emulsion with the size of 16 the insoluble dermatologic active ingredient, for example, the BPO granules, 17 okay. The Examiner made that point at several points in her Answer, and I 18 think that there's just no way to respond to that but throw up your hands and 19 say you're confusing claim elements. Certainly you could never enforce this 20 claim against somebody on the basis of the fact that their included phase 21 globule size fell within the particle range. It just -- so there's just no way the 22 claim can be tortured that way. The globule size is what the globules, one of the things that the 23

MR. MCNICHOL: Okay, yeah, and Smith, I don't have anything to

insoluble particle can't be soluble in, okay, and it's a liquid, it's fluid, it

behaves differently. It's clearly not telling any -- first of all, it isn't what

- 1 we're talking about in particle size, and it doesn't tell you anything about the
- 2 way those little granules, insoluble granules, behave when they're being
- 3 filtered out or not being filtered out by the nap of the pad, and that runs
- 4 through several of the references. And also --
- 5 JUDGE McCOLLUM: Well, I was just going to say that the
- 6 Examiner made two positions on particle size.
- 7 MR. McNICHOL: Yeah.
- 8 JUDGE MCCOLLUM: For example, you're right that, for example,
- 9 in the rejection of Smith in view of Sine, he did seem to use the globule size,
- 10 but claim 4, for example, is also rejected as obvious over Smith alone. So
- 11 his position there is not the one that you're mentioning.
- 12 MR. McNICHOL: Right.
- 13 JUDGE McCOLLUM: It's basically that it would be obvious to use
- 14 just basically these particle sizes -- optimize particle size type of argument.
- 15 MR. MCNICHOL: Yes. The particle -- out of nowhere, the
- 16 Examiner said that particle size is a result-effective variable that it would be
- 17 obvious to optimize. Where that came from, I don't know. There's nothing
- 18 in Smith that says that the particle size of the insoluble dermatologic
- 19 particles like BPO is something that affects the ability of getting that -- those
- 20 particles off the pad and onto the skin or that it's in any way a result-
- 21 effective variable. So I mean I think the law is pretty well settled that there
- 22 has to be a recognition that there's a result-effective variable, and you can
- 23 look all over Smith, and you'll never see that. It's a result-effective variable
- 24 because the Examiner said it was in light of our spec. That's it.

24

25

3 is why wouldn't smaller particles be obvious, for example, particles under 50 microns. 4 5 MR. McNICHOL: If you could answer -- ask -- if you could ask that question, okay, on the basis of something in the art other than our 6 7 specification, I think it would be a relevant question. 8 JUDGE MCCOLLUM: Oh, I'm not saying that they, you know, 9 unexpected results. I'm talking prima facie case. I mean if you --10 MR. McNICHOL: I am too. 11 JUDGE McCOLLUM: -- said yes, it's unexpected result that if you 12 had evidence of unexpected results that less than 50 is a critical or that some 13 particular number is critical, that's a different situation from just saving that, you know, it would be obvious to use basically -- I mean I guess the 14 15 Examiner's position in essence is that it would be obvious to use, you know, 16 any reasonable particle size. You wouldn't want to have particles that are 17 bigger than, you know, huge particles in your thing. 18 MR, McNICHOL: Of course, I understand that, but that's -- the 19 Examiner is saying that the limitations of those claims, okay, for example, 20 claim 5 just for example, doesn't add to the patentability of the claim, 21 because it's known to optimize a result-effective variable. That's how I understand her point, okay. Well, it's not a result-effective variable unless 22 23 there's some recognition in the art to that effect, and we've asked, we've

JUDGE McCOLLUM: You're right. The -- you know, Smith, for example, doesn't talk about the particle size. But then the question becomes

looked, presumably the Examiner has looked, and it's not there. Nobody has

pointed to anything in the prior art where there was any recognition

2

3

4

5

to do that.

7 your purpose if it's result effective for the purposes of the prior art. MR. McNICHOL: Fine. I still don't see it. It's not there, and 8 9 nobody's pointed to anything in the art. Now obviously, sure, you don't 10 want something that's the size of, you know, a BB. I mean that's 11 nonsensical, okay. But setting aside the nonsensical examples, okay, we're 12 not going to talk about baseballs and BBs and all that kind of stuff, but in 13 pharmaceutically acceptable products, okay, you have to get it small enough. But we've said within that there's a range, okay, that you have to do. This is 14 15 a special range that you have to -- and that's part of how we get to our 16 preferred embodiment which is why, you know, you have it specified in the 17 claims. And within that, no, there's no suggestion that there's anything 18 about that that would be in any way special for any purpose. There's 19 nothing in the record that would support that. 20 JUDGE MILLS: Well, I believe we understand your position with 21 respect to the particle size and if you -- looks like we're coming up on our 22 time, so if you could provide any concluding remarks that would be helpful. 23 MR. McNICHOL: Sure. I think that the viscosity, not seen in the 24 prior art. No disclosures in the prior art to that effect. I think Judge Green 25 zoomed in on exactly the point that I wanted to make, that you can't make

whatsoever that the particle size was a result-effective variable with respect

So before you ask that question, you have to be able to say the art

JUDGE McCOLLUM: Well, it doesn't have to be result effective for

recognized that this was a result-effective variable, and nobody's been able

to getting the particles off the pad and onto the skin.

1 assumptions. You can't just guess that maybe it could have been. There has 2 to be a teaching, okay, and the law is I think very clear with respect to that. 3 Delambre I think -- Delambre by the way the Examiner mischaracterizes the viscosity, and we discussed that in our reply brief at 4 5 page 25, she did great violence to the physics of viscosity. It doesn't work the way she did to make the conversions that she did both as to time and 6 7 pressure. She converted it into a pressure meeting. It was just wrong. So 8 we don't accept that the viscosity number that the -- that you see in 9 Delambre is correct as the Examiner interprets it, but either way it's not 10 ours, okay. 11 And with respect to Bissett, if I can come back to Bissett again, if 12 Bissett teaches anything, if it provides any suggestion with respect to 13 viscosity, if for some reason you were going to say that there was -- it was in 14 any way a result-effective variable recognized that way, Bissett is the only 15 teaching in the record about what you want to do with viscosity, and he says 16 go high. Go to almost 250,000, okay, and what do we do? We come in way 17 low. So if Bissett is useful for anything with respect to teaching people 18 about viscosity, he's saying don't do what Dr. Patel did, go high, and 19 Dr. Patel said uh-uh, I'm not going to do what Bissett did. I'm going to do 20 this, and lo and behold, he gets a result that not even Bissett mentions. 21 JUDGE MILLS: Okay, we're good. Any more questions from the 22. bench? No? 23 JUDGE McCOLLUM: No. Thank you. 24 MR. McNICHOL: Thank you for your time.

JUDGE MILLS: Okay, thank you very much.

## Appeal 2009-001871 Application 10/613,698

1	if you wouldn't mind helping the reporter out if he has any questions
2	regarding spellings.
3	MR. McNICHOL: Absolutely. I think I gave the reporter my card,
4	and you can e-mail me or call me with any questions
5	JUDGE MILLS: Did you have any immediate questions?
6	(Whereupon, the hearing concluded on June 25, 2009.)
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	